

Kepone
Position Document 3

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Kepone Working Group
U.S. Environmental Protection Agency

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Kepone: Position Document 3

The sole manufacturer of Kepone, Allied Chemical Company, has stopped production of this pesticide and intends to destroy its remaining stocks. Therefore, the fate of Kepone now held by formulators, or in the channels of trade, has been the Working Group's primary concern. This Kepone may be divided into two categories: (1) Kepone which has been formulated into registered products with end-use labeling and (2) stocks of 25% Kepone in the hands of formulators which is being held for conversion to registered, end-use products. This document presents an analysis of the risks and benefits of Kepone as formulated. In addition, because Kepone is no longer being produced, the document focuses special attention on a preliminary analysis of the risks and benefits associated with the use of existing stocks of currently registered end-use products, and stocks of these products which could be produced from the remaining supplies of 25% Kepone currently in the hands of formulators.

The questions about existing stocks of Kepone necessitated a continued analysis in any case. There was therefore no need to prepare a Position Document 2, since its function is to determine whether or not to proceed with the analysis.

I. Structure and Characteristics

Kepone is the trade name for the insecticide decachloro-octahydro-1,3,4-metheno-2H-cyclobuta (cd) pentalen-2-one. The common name is chlordane.

The technical product, which is over 90% pure, sublimes at 350°C; it is relatively soluble in water (0.4% at 100°C) compared to most chlorinated hydrocarbon pesticides. Kepone is also soluble in strong alkali as well as in acetone and ethanol. Kepone is very stable in vitro.

II. REGULATORY HISTORY

A. Previous Registrations, Uses, and Tolerances

The first Kepone product was federally registered in 1959. Kepone was not among the suspected carcinogens discussed either in the 1969 "Report of the Secretary's Commission on Pesticides and their Relationship to Environmental Health" (Mrak Report) or in "Suspected Carcinogens - A Subfile of the NIOSH Toxic Substances List" (June 1975).

Because of low domestic use, which was primarily nonagricultural, Kepone was given low priority on the list of pesticides for which residues were sought and on which research was conducted.

Some early registered uses of Kepone were allowed only if no residues could be detected. However, as methods of residue detection became more sophisticated, the expectation of finding no residues of any pesticide used on food crops became unrealistic. In June 1965, a committee of the National Academy of Sciences, National Research Council, evaluated the practice of registering pesticides for use on food crops on such a basis and concluded that it should no longer be allowed.

USDA and HEW decided to discontinue all uses involving any reasonable expectation of residues on food or feed at harvest by December 31, 1967 if a specific tolerance had not been set. Registrations of all food and feed crops unsupported by tolerances were phased out, unless evidence supporting a tolerance was received, or unless a Federal Agency requested its retention.

Because progress reports on tests were received before this date, certain extensions were granted. Extensions granted for Kepone were as follows: banana use (Appendix A), and uses on cropland and pasture (Appendix B).

On February 1, 1968, all uses of Kepone on Chinese cabbage, sweet corn, cucumbers, endive, lettuce, peppers, radishes, squash, sugarcane, and tomatoes were cancelled. All of these crops, except sugarcane, were treated by preplant applications of 2% Kepone bait disced into the soil at the rate of 50 lb/acre. Sugarcane was treated at the rate of 2 lb actual Kepone per acre as a bait, or 3 1/4 lb actual Kepone per acre as a spray.

The only tolerance which was established on an agricultural crop was 0.01 ppm in whole bananas on November 4, 1970 (35 FR 16980). Subsequently, a registration was granted for use of a 5% Kepone dust formulation against banana-root borers.

An Allied registration of 50% wettable powder for use as a citrus spray was cancelled by the Agency on November 1, 1974, when Allied did not request renewal of the registration.

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The other uses for which Kepone was registered did not require tolerances. These were: (1) bait use on tobacco, (2) use on turf, and (3) use of inaccessible and accessible bait formulations, primarily for ant and roach control, both inside and outside dwellings and commercial establishments. Kepone is currently registered only for ant and roach control.

On June 2, 1976, Allied Chemical Company requested cancellation of its Kepone registrations under Section 6(a)(1) of FIFRA, and on June 9, 1976 the Deputy Assistant Administrator for Pesticide Programs issued a Notice of Intent to Cancel, pursuant to Section 6(a)(1) of FIFRA, of all Allied Chemical Company's Kepone registrations (41 FR 24624). No requests were received from the registrant or from persons with the concurrence of the registrant to continue these registrations. Accordingly, all of the following registrations were cancelled, effective on July 24, 1976:

EPA Registration No.	Product Name
218-504	Allied Chemical Kepone/ Ant & Roach Paste.
218-515	Allied Chemical Kepone/ Ant Trap.
218-535	Allied Chemical Kepone/ Roach Trap.
218-537	Allied Chemical Kepone/ Ant Paste Trap.
218-539	Allied Chemical Kepone/ Insecticide Pellets.
218-540	Allied Chemical Kepone/ Insecticide Paste.
218-541	Allied Chemical Kepone/ Paste Roach Trap.
218-544	Allied Chemical 25% Kepone/Special Mixture.
218-533	Allied Chemical Kepone/ Ant and Roach Bait Pelleted.
218-566	Allied Chemical 5% Kepone Dust.
218-589	Allied Chemical 80% Kepone Concentrate.
218-605	Allied Chemical Kepone/ Ant & Roach Paste (Tube Package).

(Allied Registration #218-566 was the only current EPA registration for use of Kepone on bananas.)

A notice announcing cancellation of Allied products has been prepared (Appendix C) for publication with the notice announcing the actions herein recommended for those registrations which remain valid. This notice announces that the Allied registrations are cancelled and that the stocks of the products cannot be distributed, sold, or used. However, use of existing stocks of Allied Chemical 25% Kepone Special Mixture (EPA Reg. No. 218-544) already in the hands of formulators would be allowed for the formulation of products, pursuant to the recommendations made in this document.

The original dates of registration of the 49 Kepone products with current Federal registrations range from 1948 to 1975. Kepone was first used in a federally registered pesticide product in July 1959. Ant and roach bait products registered prior to that time contained thallium sulfate as the active ingredient. Kepone eventually replaced thallium sulfate as the active ingredient in the currently registered Kepone bait products. These products are listed in Appendix C.

Prior to the current RPAR action, pertinent literature was reviewed within the Agency, and a report on this pesticide was completed on August 23, 1975. A report of the National Cancer Institute on the oncogenicity of Kepone was released on January 16, 1976.

The dates of actions taken in the course of the RPAR process are contained in Appendix D.

B. The RPAR Notice

1. Basis for RPAR Issuance

The Kepone RPAR, which appeared in the Federal Register on April 20, 1976, was issued on the basis of tests which indicate that Kepone induces oncogenic effects in experimental mammalian species. Kepone Position Document 1 summarizes these test results and the risk analysis prepared by the Cancer Assessment Group (CAG).

2. Attempts to Rebut

Attempts to rebut may be found in Appendix E. They were submitted prior to June 10, 1976, by the following registrants:

<u>Company</u>	<u>Topic of Attempted Rebuttal</u>
Black Leaf Products Co. 667 N. State Street Elgin, Ill.	Enclosed traps
Boyle-Midway, Inc. South Avenue and Hale Street Cranford, N.J.	Enclosed traps

Clarence Board and Sons, Inc.
105 E. Commerical
Leon, Iowa

Enclosed traps

Lethelin Products Co.
15 MacQuesten Pkwy., S.
Mount Vernon, N.Y.

Enclosed traps
and unenclosed
bait formulations

O. E. Linck Division
Walco Link Corporation
1234 State Highway 46
Clifton, N.J.

Enclosed traps

The Kepone Working Group determined that submissions of the Black Magic Company, Jacksonville, Fla., and the J & F Manufacturing Company, Houston, Tex., did not constitute attempts to rebut. This was confirmed by telephone conversations with company representatives. These submissions, and a comment on the Agency's cancer policy, may be found in Appendix F. A complete listing of all Federal registrants of Kepone may be found in Appendix G. Those not cited above did not respond.

3. Applicants for EPA Registration

Of the four State-registered products for which application for Federal registration had been made, three have not been formulated for years, and the companies have voluntarily requested withdrawal of their applications. The fourth company could not be located and is presumably out of business. Therefore, applicants for Federal registration are not a factor in the RPAR process.

III. SCIENTIFIC ANALYSIS OF REBUTTAL ATTEMPTS

A. Criteria and Evaluation Division (CED)

The analysis considered only evidence submitted with rebuttal attempts and did not constitute a complete risk assessment. Rebuttal attempts alleged that human exposure to Kepone is low. A preliminary review by CED of evidence submitted in support of rebuttal attempts (Appendix H) indicated that exposure to humans from household use of enclosed traps containing Kepone would be low. A summary of registrant comments was compiled. Exposure by means of ingestion and inhalation was assessed. The preliminary assessment concluded that the exposure to Kepone from such use is negligible. The report nevertheless noted that additional data, such as the concentration in air as a result of vaporization from ant traps and the concentration of Kepone in food and on kitchen utensils, would have to be obtained to assure that the traps presented no risk to humans.

B. Cancer Assessment Group (CAG)

The Kepone Working Group has decided that CED should attempt to estimate the human exposure to inaccessible traps with submitted evidence (see Section A, above). CAG, which previously verified the scientific validity of the oncogenic studies upon which the RPAR was based, was reorganizing when the rebuttal attempts were received, and therefore was not asked to assess them.

C. Discussion

The Kepone Working Group determined that a complete analysis of the risks and benefits of Kepone use would have to be completed before it could determine whether to permit the use of current stocks. The term "stocks" throughout this position document refers both to the 25% Kepone Special Mixture (Allied registration 218-544) from which other products are manufactured, and to formulated products for repackaging or sale. In addition, the Working Group decided that the apparently different risks of "accessible" and "inaccessible" products required separate consideration. The Working Group defined "inaccessible" products as all enclosed traps made from metal or plastic, as well as metal stakes containing Kepone baits which are hammered into the ground. "Accessible" products are those which would be removed from their containers, as well as foil- or cardboard-covered traps. Therefore, the Working Group requested independent benefit and risk assessments from CED and a risk assessment from CAG.

IV. SUMMARY OF RISK ANALYSES

Risk analyses were conducted by both CAG and CED. Estimates of the possibility of humans developing cancer differed because different assumptions were used in assessing data. Both groups noted that many assumptions had to be made because only minimal information on actual human exposure to Kepone products was available; techniques for assessing the magnitude of cancer risk to humans solely on the basis of animal data are very crude due to the uncertainty of extrapolation from dose-response data in animals to the very low doses to which human would likely be exposed, and also due to the different susceptibilities of animals and humans. Hence, the estimates of possible risk should be regarded only as rough indications of the effect of Kepone on humans. These estimates include not only a "worst case" in which all Kepone stock now held by formulators would find its way into human systems, but also more plausible estimates of exposure. No safety factors were used in the extrapolation models to adjust for possible differing susceptibilities between animals and humans.

Only linear extrapolation was done because available exposure data was limited. Use of nonlinear extrapolation methods would require rough estimates not only of average exposures but also of the distribution around the average. This is a particular problem in the present case, since accidental ingestion by children may be a significant portion of the total human exposure. Use of the linear extrapolation model at the rate of exposure indicated by available data would be expected to produce a higher estimate of risk than would the nonlinear method.

The amount of Kepone currently held by all registrants, except Allied Chemical Company, had to be estimated before risk/benefit analyses for remaining supplies of Kepone could be done. The twenty-three registrants were polled, and fifteen reported. In order to include all possible Kepone for a high estimate, it was assumed that the eight registrants who did not report held as much Kepone as the fifteen who did. Thus it was assumed that the registrants held 538.8 lb actual Kepone. Of this amount, it was speculated that 22.8 lb was formulated into 0.125% Kepone baits for home use; the remainder was 25% Kepone for manufacturing use. All risk analyses were based on this high estimate.

The Working Group believes that this estimate is inflated because it was generally the smaller companies who did not report. In addition, some of this Kepone has been formulated, and some formulated products have been sold to retailers since the estimate was made in early June. Therefore, two other estimates were made in the benefit analysis (Appendix I). For a medium estimate it was assumed that the eight registrants who did not report held one-half as much Kepone as the fifteen who reported. For a low estimate it was assumed that the firms that did not report held one-fourth as much Kepone as those that did. The Working Group believes that the actual amount of Kepone held by the registrants is between the medium and low values. It is reasonable to assume that the public uses these products soon after purchase rather than storing them. This fact, together with normal deterioration of inert ingredients in formulated products and the stocking practices of retail outlets, probably means that the amounts of Kepone now on retail shelves and held by the public are small.

Based upon these assumptions, the Working Group believes that the estimate of 538.8 lb of actual Kepone held by formulators which was used in assessing human risk may approximate the total amount of Kepone at all marketing levels as well as that now held by the public.

Three years are believed to be adequate for complete formulation, packaging, and sale of all inaccessible Kepone bait products. Risk analyses indicate that hazards posed by the use of 0.125% Kepone traps made from the remaining supplies of 25% Kepone over this 3-year period are slight.

Our recommendation is to permit the formulation of only the present supplies of 25% Kepone and the distribution and sale of only those 0.125% Kepone products now extant and those which can be formulated from existing supplies of 25% Kepone. Importation by registrants of additional Kepone from foreign sources during and after the 3-year period would add to the total human exposure and would not be permitted.

The Kepone Working Group was apprized of the potential problems with regard to disposal of Kepone products if some part of remaining stocks were no longer permitted to be marketed.

The Solid Waste Management Program suggested to the Office of Pesticide Programs that because of disposal problems the 6/17/76 Notice of Intent to Cancel Allied Chemical Company's Kepone products be amended to provide for the legal use of certain Kepone products (Appendix J). Problems cited in insuring proper disposal were:

1. The disposal of pesticides is the responsibility of the owners. Under existing legislation the Agency has no authority, except in the case of suspension, to require supervision of disposal.
2. Appropriate disposal methods and facilities are not readily available, and many states do not have land disposal sites approved for pesticide disposal.
3. There are significant obstacles to the movement of Kepone materials across State lines for the purpose of disposal.

The comments of the Solid Waste Program are relevant to our recommendations with regard to possible disposal of the Kepone products the registrations of which are subject to the outstanding RPAR. The constraints of disposal of such products and the potential hazard resulting from improper disposal were therefore discussed by the Working Group.

It was decided that the potential hazard of human exposure to accessible Kepone products in the home outweighed any possible hazard which might result should improper disposal occur in some instances.

As of June 9, 1976, only a small fraction of the Kepone held by formulators was in the form of accessible products (estimated at 11.4 lb actual Kepone). While additional accessible products have no doubt been manufactured since

that date, it is believed that the major portion of Kepone stocks on hand are in the form of 25% Kepone for manufacturing use and in inaccessible traps.

The impact of our recommendations, if implemented, upon Kepone residues in the Chesapeake Bay is believed to be minimal. Only the formulated accessible products and that portion of 25% manufacturing-use Kepone which can be converted to inaccessible traps would eventually be released into the environment. If our estimate of 538 lb of actual Kepone reflects the amount held by formulators and retailers, we believe that most of this amount could be formulated into traps which could be marketed for 3 years.

Many, but not all, of the formulators are located in either the Northeastern or the Southeastern states. None are located in the area surrounding the Chesapeake Bay. Retail outlets are, of course, scattered across the country. The disposal of used Kepone products by consumers at incinerators, dumps, or landfills at many locations, and the low concentration of the traps make the likelihood of a high concentration in any one location improbable.

Even given the impossible situation of 500 lb of Kepone from 0.125% bait products eventually finding its way to the Chesapeake Bay, this amount would be miniscule when compared to the 100,000 lb of Kepone which the Virginia Institute of Marine Science estimates is contained in James River sediment between Hopewell and Newport News, Va. Additional unknown amounts of Kepone have entered the Bay. Another 500 lb is certainly not desirable, but this amount would add little to the levels now found in Chesapeake seafood.

A. All 0.125% Kepone Products -- CAG Analysis

1. Effects on All Household Members

CAG based its extrapolation of possible carcinogenic effects upon the number of people who would be exposed over a 3-year period to the current Kepone stock estimated to be held by formulators (Appendix K). CAG estimates that, if all the Kepone now available were absorbed into the bodies of purchasers of Kepone products, there would be a total of 540 additional cases of human cancer in the exposed population.

Obviously, this represents an impossible situation. By contrast, the same model and animal data were used by CED, but they were applied at the 95% upper confidence limit of one of the statistical parameters; this resulted in a somewhat higher "worst case" estimate (718.5 carcinomas). If it is assumed that 0.1% of the Kepone in the current stocks were ultimately absorbed into human systems, the probability that just one person among the entire exposed group would develop a carcinoma is 0.5. This calculation is based on the assumption that the effect of exposure to Kepone would be the same if a dose were taken in a single accidental ingestion or ingested over a period of several years.

This calculation does not take into account that a child's exposure and susceptibility to Kepone products may be different from an adult's. Because of the long latency period between exposure to a carcinogen and the development of a cancer, there is a higher probability that a child would live to the onset of cancer symptoms than would an adult.

2. Effects on Small Children from Ingestion

Data from the Pesticide Episode Report System (PERS) shows an average of 12.5 cases per year involving young children and Kepone products (Appendix L). In almost all episodes involving traps, the children were found chewing the can without any indication that they had ingested the contents. If only 1% of the actual cases were reported, there would be 1,250 such cases per year, or approximately 3,750 cases over a 3-year period. If it is assumed as a worst case that an average of half the contents of a trap (approximately 4 g) were ingested, then each child would have eaten 5 mg of Kepone or about 6.7 ppm in his diet for that day. If 3,750 children ingested this amount, an expected 0.083 cases of cancer would result. This means that 3,750 children would have to be exposed as postulated for there to be one-twelfth of a chance that just one child among them would develop a carcinoma.

On the one hand, CAG described the assumption that only 1% of all Kepone poisonings are reported as "probably pessimistic." A higher percentage of such incidents, in their view, would probably be reported. On the other hand, it is possible that many cases of ingestion and dermal exposure to accessible Kepone products are undetected. In that instance, the 1% estimate would appear more reasonable.

B. Inaccessible Traps: CED Risk Analyses

Table 1 presents a range of estimated exposures and the number of carcinomas which could be expected from these exposures if all assumptions were correct (Appendix M).

TABLE 1: Carcinogens Projected from Exposure to Various Amounts of Kepone From Inaccessible Traps

Daily Exposure Levels (a) (ug Kepone/ kg body weight)	Total Kepone (mg) Absorbed (b) (a x 60 kg x 1095 days)	w (b/270 mg)	Number of Carcinomas (N) 718.5x(w)
4.1	270	1	718.5
0.5	32.9	0.12	86.5
0.07	4.7	0.017	12.2
0.017	1.1	0.004	2.9
0.00002	0.0014	0.000005	0.004

The highest and lowest figures in Table 1 were derived as follows:

"Worst Case" Assumption (718.5 carcinomas): All Kepone present in three traps (270 mg) is retained in the tissue of a single human weighing 60 kg who is exposed 12 hours a day in a 30 cubic meter room for 3 years. It was assumed that the room contained three traps which were replaced every 3 months over a 3-year period and that a total of 900,000 people would be so exposed.

"More Likely" Assumption (0.004 carcinomas): The same conditions of exposure are assumed. Available data on the evaporation rate of DDT, which has a vapor pressure in the same range as that of Kepone, are used, and the rate of evaporation is assumed to be proportional to the concentration of Kepone.

The CED analyses primarily address exposure by inhalation. In the "worst case" assumption, total retention of all Kepone would involve ingestion or inhalation of all the Kepone contained in each of the 36 traps by each of 900,000 adults weighing 60 kg. Such an occurrence is clearly impossible.

Exposure to 0.00002 ug Kepone per kilogram of body weight per day, resulting in 0.004 cases of carcinoma in the exposed population, was felt to be "more likely." Even this estimate does not take into account the enclosure of the bait in traps (which would restrict air movement), replacement of the air, use of the room by more than one person, and use of the room for less than 12 hours, all of which would affect exposure. The analysis concluded that "it is not possible to guess whether the numbers so calculated are even within the orders of magnitude of the real value."

The danger to children from ingestion of Kepone in traps was not addressed by CED. The possibility that a child, or anyone, might be exposed to Kepone dissolved by water or in deposits on dishes, pans, and eating utensils was judged to be remote.

C. Accessible Products

Kepone baits wrapped in foil or cardboard are considered accessible products, although risks of exposure from such products may be different from risks of exposure from jellies and other open baits.

1. CED Analysis

The CED analysis (Appendix M) is directed to the hazard from inhalation of Kepone. The same assumptions were made about room size and total time exposed as were made in the CED analysis of hazard from Kepone traps.

The estimate of Kepone exposure was based on the surface area of impregnated bread crumbs, because bread crumbs present the greatest surface area of the various types of accessible bait products. CED assumed that users would apply 1 oz of formulated bait per week, or a total of 5.5 g Kepone in 3 years.

Making the same assumptions as in the above-mentioned "more likely" situation with regard to exposure from traps, CED derived the values below:

Daily Exposure Levels (a) (ug Kepone/ kg body weight/ day)	Total Kepone Absorbed (b) (a x 60 kg x 1095 days)	w (b/5.5 g)	Number of Carcinomas (N) 718.5x(w)
0.00065	0.043	0.00001	0.007

CED concluded that when Kepone products are used according to the label for a 3-year period, there is no significant risk of cancer from inhalation of Kepone from accessible bait products. CED did not assess dermal or oral exposure.

2. CAG Risk Assessment

CAG estimated the highest risk to an individual from the "worst likely exposure" by assuming that a small child would eat six 3-oz tubes of 0.125% Kepone ant paste over 3 years (Appendix K). This child's daily food consumption was assumed to be about 0.75 kg. Extrapolating from the NCI animal test results, CAG estimated the probability that this child would contract cancer to be about 0.25%. This means that 400 children would have to be exposed to this high amount for there to be an expected case of cancer. This estimate was depicted as the worst possible case. CAG states that only a small number of children are likely to be exposed at this level.

V. SUMMARY OF CED BENEFIT ANALYSIS

Because the Kepone registrations of Allied Chemical Company have been cancelled, the only remaining issue of economic consequence is the use of current stocks of both 25% manufacturing-use Kepone and 0.125% formulated Kepone products.

Analysis of alternatives for ant control indicates that Kepone bait is the most expensive treatment. Diazinon and other alternative insecticidal sprays are more economical (Appendix I). Controlling roaches in domestic dwellings with Baygon bait is more expensive than with Kepone bait, but alternative sprays cost about one-fourth to one-half as much as Kepone bait treatments. In general, alternative sprays are less costly than Kepone bait for control of ants and cockroaches in domestic dwellings. The loss of Kepone for control of ants and cockroaches would result in reduced cost to the consumer, except where Baygon bait was used against roaches. However, neither the inconvenience of shifting from baits to sprays nor the possible additional costs of repeated spray applications were included in these cost estimates.

The executive summary that appears in the CED benefit analysis contains estimates of impacts on consumers from regulatory options.

EPA's Interim Guideline for Economic Impact Analysis of Proposed Regulatory Actions to Control Carcinogenic Pesticides states, "The impacts on pesticide manufacturers are not germane to this type of regulatory decision, in which the risk of the use of a pesticide is compared to the benefit of that use" (41 CFR 21405). The term "manufacturers" has been interpreted by the Kepone Working Group to mean all manufacturers, formulators, distributors, retail outlets, and pest control operators. Therefore, although the impact of this action upon the formulators and distributors of Kepone products was discussed in the Benefit Analysis, it has not been considered in the pros and cons of options available to the Agency with respect to the rebuttable presumption.

VI. EVALUATION OF RISKS AND BENEFITS

A. Comparison of Risks and Benefits Should Manufacture and Sale of Kepone Products Be Permitted Indefinitely

Since Allied Chemical Company has voluntarily requested cancellation of its manufacturing-use-only products, the Working Group felt it was unlikely that humans and the environment would be exposed to more than the supplies of Kepone currently in existence. Therefore, the risk analyses focused on the risks of allowing sale, distribution, and use of existing stocks of formulated, end-use products, and stocks of formulated, end-use products, which could be produced from stocks of manufacturing-use-only Kepone products currently in the hands of formulators. However, since it is possible to formulate end-use Kepone products under existing registrations without access to manufacturing-use-only Kepone products, the Working Group also had to concern itself with the risks of indefinite use of Kepone under existing registrations. Although the numerical risk extrapolations performed for the Working Group address only the risks associated with the sale, distribution, and use of existing supplies of Kepone, it is the opinion of the Working Group that unlimited sale, distribution, and use of currently registered end-use Kepone products into the indefinite future would increase the risk of oral, dermal, and inhalation exposure without any corresponding increase in benefits. For this reason the Working Group believes that unlimited use of Kepone under its current registrations into the indefinite future would result in unreasonable adverse effects on humans and the environment.

B. Comparison of Risks and Benefits Should Manufacture and Sale of Kepone Products Be Permitted for 3 Years

Because CAG has determined that Kepone is a likely human carcinogen, both CAG and CED predict some human risk from the household use of all currently registered bait formulations. Hazards from accessible products are believed to be greater than those from traps.

We do not know the precise amount of formulated Kepone which now exists within the product distribution system. A rough estimate of the maximum amount in the possession of formulating firms is 537.8 lb actual Kepone (Appendix K). As indicated above, this number is a conservative estimate which probably overstates the amount of Kepone in the hands of formulators to a sufficient extent to allow us to assume that this number also covers the amount of Kepone in channels of distribution. Discussions with formulators indicate that in 3 years all existing Kepone stocks will be depleted. For most firms the time necessary for depletion of stocks should be much less. The length of time consumers will be exposed to Kepone products remaining on retail shelves should be no longer than 3 years if formulators recall these products at the end of that time.

As noted previously, the risk assessments are based upon many unknowns, including the actual amount of Kepone now held by distributors, retail outlets, and the public. The benefit analysis and all risk analyses were based only upon a "worst case" estimate of stocks held by formulators.

1. Inaccessible Traps

The human risk of exposure by inhalation of Kepone from inaccessible products is judged to be low. The dermal and oral exposure of children is also judged to be low. Data from the Agency's Pesticide Episode Reporting System indicate that, between December 1971 and the present, there were 52 reported incidents of contact of young children with baits containing Kepone (Appendix L). A majority of these incidents involved traps. In only a few of these incidents did the children actually ingest the bait. No symptoms were reported in any of these incidents. One of two dogs accidentally poisoned by Kepone baits, however, was hospitalized with tremors. Although all such incidents are not reported, the data indicate that children can and do open some traps. CAG has concluded, however, that the risk of the formation of a single carcinoma in a child from these known ingestions is very low.

Based upon these risk analyses, the Kepone Working Group concludes that human risk from the use of all current Kepone Stocks when formulated into traps is extremely small if used for only 3 years.

The CED benefit analysis determined that benefits conferred by the continued use of Kepone products were minimal. The efficacy of accessible and inaccessible products were assumed to be the same. Registered alternative chemicals for insect control are slightly less costly but are also less convenient for the homeowner to use. The relative efficacy of alternatives and Kepone baits is difficult, if not impossible, to establish. The alternative sprays are not exact substitutes for Kepone baits because baits are carried back into the nests. Thus, many insects presumably do not have to come into contact with the treated site to be affected. A bait may also be placed away from the point of infestation and attract insects to it. One alternative, Baygon, is currently registered as a bait formulation for use against roaches but not ants.

The benefit analysis contains a list of registered alternatives. Among these are some recommended by a number of States for use in controlling ants and roaches. A State recommendation reflects the best thinking of entomologists in that State as to which insecticides will effectively control the given insects. The following registered alternatives are most commonly recommended by State Extension Services for control of ants and roaches: Baygon, malathion, ronnel, and chlordane.

Of these insecticides, chlordane is currently the object of an administrative hearing to determine whether or not to continue registration for this and other uses. Of the other insecticides, only ronnel is presently being considered as a candidate for the RPAR process. Total exposure of the population would diminish greatly over the 3-year period as stocks of Kepone were depleted, with consequent reduction and eventual termination of any health hazard to the consumer. The availability of enclosed Kepone traps during this period would continue to provide homeowners any unique benefits of these products until another bait product could be registered for ant control. Health risks from the use of these products appear to be extremely low.

2. Accessible Products

CED has found risks from inhalation of accessible products to be very low, although not as low as the inhalation risks from inaccessible traps. The CAG analysis includes an estimate of projected carcinomas from a worst reasonable exposure to Kepone products by young children. This estimate assumes that if 400 children ingested six 3-oz tubes of accessible paste over 3 years, one additional case of cancer could be expected to occur.

CAG also estimated that if each of 3,750 children ate one-half of the contents of a trap (4 g), the probability of one carcinoma occurring in just one child would be 0.083. This calculation was based upon PERS accident data of all reported incidents of contact with any type of Kepone product. Although hazard from accessible bait formulations is believed to be greater than that from traps, data from PERS showed that reported cases of contact by small children with Kepone traps outnumber those of contact with accessible formulations. This may be because children playing with or attempting to open a trap are readily detectable, while even if a child ingests an accessible product there are not likely to be any detectable symptoms (Appendix L).

The CED risk analysis noted that decreased air movement inside a trap would reduce the evaporation rate of Kepone. Similarly, the possibility of exposure through other routes would be less for traps than for the accessible products.

It is apparent that factors inherent in the nature and method of application of accessible products render them more likely than inaccessible bait to result in human exposure.

Accessible products and, to a lesser extent, foil- and cardboard-enclosed bait products would seem to present a greater hazard for the following reasons:

1. Inhalation exposure to the Kepone in accessible products, although very low, is greater than exposure to Kepone in traps during the application and life of the product.
2. Dermal and oral exposure to accessible products is greater than that to traps during application, use, and disposal.
3. Oral exposure to children is greater because the contents are readily accessible if the bait is either stored or applied in areas they can reach. The inert ingredients, which are generally sweet in order to attract ants or roaches, may also make the bait appealing to young children.
4. Accessible bait, once applied, cannot be removed as easily as an enclosed trap. Once an accessible product is applied to cracks and crevices it may be difficult to wash away and may persist in the home environment for years. Kepone is a highly persistent substance and does not readily degrade.

5. Accessible formulations can be smeared or scattered almost anywhere, whereas the contents of closed cans are almost immobile. Although label precautions state that accessible baits should not be applied to areas that children or animals can reach, there are contradictory directions on some labels which direct the user to apply the pesticide to window sills, baseboards, and similar areas. A lack of caution by some users may also result in improper storage or application. The risk analyses could not and did not take these factors into account.

Benefits from accessible Kepone products are assumed to be the same as those of Kepone traps. The length of effectiveness of these products is contingent on the effective life of the attractants in the formula. If stocks of accessible products are permitted to be manufactured and sold for 3 years, users would benefit from any control advantages conferred by bait formulations. The benefits of both accessible and inaccessible products are believed to be slight, however.

The risks of the use of current stocks of accessible products, although difficult to quantify, appear to outweigh the benefits.

C. Comparison of Risks and Benefits Should Manufacture and Sale of Kepone Products Be Permitted for 1 1/2 Years

1. Inaccessible Traps

A 1 1/2-year limitation would not materially affect the already low human risk from these products. In fact, most formulators have indicated that their current supplies will be depleted by that time.

Any short time limit on the formulation and/or marketing of Kepone products by formulators may result in accelerated formulation and sale to distributors and to retail outlets. The risk to the public would probably remain about the same because the exposure would not greatly diminish.

If marketing outlets cannot or will not absorb more Kepone traps, then imposition of a time limit would result in less risk of human exposure to Kepone.

At the end of any imposed time limit for formulation and marketing, if the goal is to reduce risks, all marketing and distribution by formulators must cease, and a recall of products already sold by formulators must be issued. Obviously such a determination by the Agency now would not be conducive to sales to distributors and retailers, especially toward the end of the time period. Should a recall of products also be issued to formulators after 1 1/2 years, risk would be reduced relative to the amount of Kepone removed from the market.

The over all reduction in hazard cannot be estimated since we do not know what Kepone stocks are held by distributors and retail outlets or what percentage of current stocks can be marketed by formulators in a given time. The hazard, however, has already been presumed to be very small.

In summary, loss of benefits would be minimal, and there would be little reduction in risks.

2. Accessible Products

The risk from accessible products is greater than that from inaccessible traps. With that difference, the comments for a 1 1/2-year time limit of traps are appropriate here also. Loss of benefits from the unavailability of accessible Kepone products would be minimal, and there would be a very slight reduction in risk.

D. Comparison of Risks and Benefits Should Distribution and Sale by Formulators Cease Immediately and Existing Stocks be Recalled

1. Inaccessible Traps

The very slight risk from these traps does not appear to warrant this action. A decision to prohibit immediately all use of inaccessible traps would require the same action against accessible products. The benefits of ant baits would then not be available to the public.

Although slight, benefits would be more affected by this action than by any other option. The low risk of these traps, when compared to a relatively greater hazard from accessible products, would render untenable any decision to stop immediately the sale of inaccessible traps, without the inclusion of the accessible products.

2. Accessible Products

The amount of additional dermal and oral exposure could not be reliably estimated. Active Kepone constitutes only 0.125% of these products. Nevertheless, the possibility of exposure of all members of a household, especially small children, to a likely human carcinogen in a formulation that enhances exposure by several routes presents a discernible risk. Immediate recall is the only option which would remove this risk. This option could be exercised without the same action being taken against inaccessible products.

Partial information on current stocks of formulators indicates that approximately one-half of the known formulated stock is accessible bait. Continued registration of traps would provide the public the benefits of bait control to the extent that these traps are available. If formulators have EPA registrations for both types of products, they may be able to use all their 25% manufacturing grade Kepone solely to produce traps. Only a few firms are in this category, however.

VII. ALTERNATIVES

A. Continued Registration of Kepone Products

The Working Group does not consider the continued registration of any Kepone product a desirable alternative for the following reasons:

1. CAG has concluded that the animal tests reviewed present significant evidence that Kepone is likely to be a human carcinogen.
2. However slight the exposure from ant and roach baits, indefinite continuation of such exposure to a suspected carcinogen would produce a long term risk which could be justified only if benefits were substantial. This does not appear to be the case.
3. The Kepone Working Group has determined that none of the comments submitted in response to the RPAR notice rebutted the presumption that Kepone is an oncogen.
4. There are alternative methods of controlling ants and roaches which appear to be less expensive than Kepone bait applications.

5. Allied Chemical Company's voluntary cancellation of its registration has cut the Kepone supply to all formulators. Continued registration of end-use products may encourage registrants to seek new domestic or foreign sources of Kepone.

B. Cancel Registrations of Kepone Products

The Working Group recommends that the Agency issue a notice of intent to cancel all Kepone products for the reasons listed above. If issued, such notice must include a determination of whether, and how long, marketing and use of currently existing stocks of registered, formulated products will be permitted. We should also consider whether, and how long, to permit existing stocks of 25% Kepone, presently in the possession of registrants, to be formulated into registered end-use products. These products could then be distributed during any period decided upon for marketing existing stocks of end-use products. The two types of products, accessible and inaccessible, should be considered separately.

1. Permit the Formulation and Sale of Kepone Products for 3 Years, Enabling Essentially All Current Stocks to be Formulated and Sold, Recalling All Remaining Stocks at the End of the 3 Years.

- Pros
1. Data from the oncogenic studies cited in Position Document 1 served as the basis for issuance of the Kepone RPAR. OPP did not presume against Kepone because of any of the criteria tied to human exposure. However, Kepone baits contain little active ingredient, and exposure seems to be very low.
 2. The total amount of active Kepone held by formulators is estimated to be low.
 3. Permitting the formulation of 25% Kepone to 0.125% baits would eliminate a major problem of disposal.

- Cons
1. The 3-year maximum time necessary for depletion of available Kepone stocks is much greater than the time allowed for sale of DDT, aldrin, and dieldrin when these products were cancelled or suspended.

2. Because the Agency believes Kepone to be a potential carcinogen, permitting any continued human exposure, even though this exposure may be slight, may imply a lack of proper concern for the public welfare.
3. The reaction of environmental groups, which have insisted that EPA confiscate stocks of other compounds in the past, must be considered.
4. The time for complete sale of stocks in retail stores may well take more than 3 years.
5. Estimated risk from use of accessible products precludes consideration of these products in this alternative.

Note that a determination by the Agency that a recall^{1/} would be made at the end of the 3-year period may result in accelerated marketing and reduced pricing at all sales levels toward the end of the allotted time. A recall, however, is the only way to ensure that Kepone products will be removed from the marketplace at the end of 3 years.

2. Permit Sale and Formulation of Stocks for 1 1/2 Years

- Pros
1. The oncogenic hazard may warrant a time limit.
 2. An adequate time allowance may permit use of most of the current stocks at the same time reducing the likelihood of their appearance in retail outlets many years later.
- Cons
1. EPA must commit enforcement resources to retrieve Kepone stocks from all distribution points after expiration of the time limit.
 2. Disposal of unsold products at the end of 1 1/2 years would be a problem.

^{1/}. EPA does not have the legal authority to require the recall of cancelled or suspended pesticides (see Appendix N); however, EPA has initiated several hundred recall actions which registrants have almost always voluntarily accepted. Moreover, if voluntary recalls fail, EPA has the authority to issue Stop Sale, Use, and Removal Orders pursuant to Section 13(a) or to engage in seizure actions pursuant to Section 13(b) of FIFRA.

3. This alternative, without imposition of a recall at the end of 1 1/2 years, would not reduce human risks, since formulation and sale would probably accelerate.
4. If a recall were to be imposed in only 1 1/2 years, distributors and retail outlets would probably not buy Kepone products.

3. Immediate Cessation of Formulation and Sale;
Recall Products

a. All Products

- | | |
|-------------|---|
| <u>Pro</u> | 1. All risk would be eliminated. |
| <u>Cons</u> | 1. Minor benefits of inaccessible Kepone baits would not be available to the public. |
| | 2. Disposal of formulated Kepone and 25% Kepone for manufacturing use would be difficult. |
| | 3. EPA must commit enforcement resources to retrieval of Kepone products. |

b. Accessible Products

- | | |
|-------------|--|
| <u>Pros</u> | 1. Immediate action against these most hazardous formulations may result in less outside pressure to reduce the time period for use of inaccessible baits. |
| | 2. Limiting this action to the most hazardous products should all but eliminate human risk. |
| <u>Cons</u> | 1. The relatively small amount of Kepone so formulated may not warrant such an effort. |
| | 2. PERS data indicate that inaccessible traps account for many of the exposure incidents. |

C. Recommendations

The Kepone Working Group recommends that the Agency issue a notice of intent to cancel the registrations of all Kepone products. It further recommends that all sale and formulation of accessible Kepone products, as well as cardboard or foil traps, be stopped and that all such products held by formulators be recalled. Manufacturing grade Kepone should be permitted to be formulated into ant or roach baits for enclosure into metal or plastic traps and marketed for a period of 3 years. At the end of this time, all remaining stocks held by formulators should be subject to stop sale, and products held by distributors and retail outlets should be recalled.

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